

REMARKS

The present communication responds to the Office Action mailed August 2, 2001 for the above-identified application. The Examiner issued a restriction requirement regarding claims 26-80, indicating that the claims were directed to three patentably distinct species. The Examiner asserted that the patentably distinct species of the claimed invention were as follows: the pace-first-then-defibrillate after sensing a hemodynamically compromising malfunction species represented by claim 26, the defibrillate-first-then-pace after detecting an arrhythmia species represented by claim 36, and the pace-first-then-defibrillate after sensing an arrhythmia species represented by claim 42. Applicants object to the pace and defibrillate language as mis-descriptive of the invention.

The Examiner further stated that claim 73 set forth arrhythmia detection but hemodynamic malfunction detectors and represented an erroneous or hybrid species which could not be grouped. It is noted that the Examiner did not address independent claims 59, 67, or 78.

Applicants have cancelled claims 26-35 and claims 36-80 and have added new claims 81-140.

We have carefully reviewed the Examiner's reasons for restriction requirement and respond as follows:

Provisional Election

The Examiner appears to have based his restriction requirement on two perceived distinctions: that between "hemodynamically compromising malfunction detection" and "arrhythmia detection"; and that between "pace-first-then-defibrillate" and "defibrillate-first-then-pace." Applicants traverse these distinctions, however, to the extent that these distinctions are maintained, applicants would like to elect a species claiming "defibrillate-first-then-pace" after "hemodynamically compromising malfunction detection." Applicants provisionally elect, with traverse, the species embodied by claim 36, as amended.

Traversal

This invention involves a method and device for treating a patient that is experiencing a hemodynamically challenging malfunction by providing a series of electrical current pulses wherein the pulses have a voltage less than that which would defibrillate a heart and a series of pulses including at least one pulse having a voltage that is more than that which would defibrillate a heart.

Applicants assert that "hemodynamically compromising malfunction" is generic and includes arrhythmia; an arrhythmia is a form of a hemodynamically compromising malfunction. If the Examiner does not feel that "hemodynamically compromising malfunction" is generic and includes arrhythmia, applicants elect the claims drawn to hemodynamically compromising malfunction detection.

Further, the treatment involves delivering a series of pulses having at least one pulse with defibrillatory voltage and delivering a series of pulses wherein the pulses have a voltage less than defibrillatory voltage. This may involve providing pulses having a voltage less than defibrillatory level first and then providing pulses including at least one pulse having a defibrillatory level voltage second or may include providing pulses including at least one pulse having a defibrillatory level voltage first and then providing pulses having a voltage less than defibrillatory level. While the treatment involves providing both series of pulses, it is generically order non-specific. This is evidenced by the device claim (old 42 claim; new claim 117) that requires an internal defibrillator and circuitry for delivering electrical current pulses having a voltage level less than the voltage necessary to defibrillate the patient. No element of the device claim speaks to the order in which the series of pulses should be delivered.

In response to the restriction requirement imposed in the pending Office Action, Applicants respectfully traverse the distinction between "arrhythmia detection" and "hemodynamically compromising malfunction," maintaining, instead, that "arrhythmia" is a sub-set of "hemodynamically compromising malfunctions." Applicants further traverse the restriction requirement between "'pace-first-then-defibrillate" and "defibrillate-first-then-pace," asserting that the delivery of the series of pulses is generic. If the Examiner chooses to maintain the requirement, Applicants elect the species drawn to providing

pulses including at least one pulse having a defibrillatory level voltage first and then providing pulses having a voltage less than defibrillatory level.

Regardless, Applicants provisionally elect the species represented by claim 36, as amended. The Commissioner is hereby authorized to charge any additional filing fees required to Deposit Account No. 061910. If any additional fees are required to enter the present amendment, Applicant hereby authorizes the Office to charge our deposit account, Deposit Account No. 061910. If the Examiner feels that prosecution of the present application can be materially advanced by a telephonic interview, the undersigned would welcome a call at the number listed below.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

36. (Amended) A method for forcing [producing minimal] cardiac output during hemodynamically compromising malfunction [on an emergency basis] in a patient [experiencing arrhythmia], comprising the steps of:

- (a) positioning a plurality of electrodes to enable delivery of electrical pulses which will be transmitted within [through portions of] the patient's body [heart];
- (b) providing circuitry [means] for detecting the presence of a hemodynamically compromising malfunction [arrhythmia] in the patient;
- (c) detecting the presence of a hemodynamically compromising malfunction [arrhythmia] in the patient;
- (d) delivering a series of pulses [defibrillation pulse within] through the patient's body, the series including at least one pulse having a voltage of a normal defibrillation voltage level; and
- (e) delivering electrical current pulses through the patient's body, [via said electrodes after said defibrillation pulse delivery and after detecting arrhythmia, said] the electrical current pulses having a voltage [greater than that which would only pace the heart and] less than a normal defibrillation voltage level [that which would defibrillate the patient's heart], [so as] to force [some] contraction in the patient's muscles [heart, whereby] and to facilitate a minimum level of cardiac output [is maintained] until cessation of the hemodynamically compromising malfunction [arrhythmia] or until other medical intervention is provided.